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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,722	12/06/2001	Kei Roger Aoki	16952CON1DIV5CIP1	5741

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EXAMINER	
GUPTA, ANISH	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/008,722	AOKI ET AL.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-17, 19 is/are rejected.

7)☒ Claim(s) 18 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

H/L

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2-25-05 has been entered.

2. The rejection made in the previous office and not cited herein is hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-16 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended to recite that the botulinum toxin is administered to a human patient "at a location inferior to the nose of the patient."

Lack of Ipsis Verbis Support

The MPEP stats "[w]hen an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the

support for any amendments made to the disclosure." In their response, Applicants failed to specifically point out he support for the amendment made. In reviewing the instants specification, the disclosure fails to provide any literal support to support the claimed amendment that administration is achieved at a location inferior to the nose of the patient. On page 12 of the disclosure, modes of administrations are described but the disclosure fails to disclose that administration is achieve only to those locations inferior to the nose.

Lack of Implicit Support

It is acknowledged that the specification can provide support for a claimed amendment via implicit or inherent disclosure. However, the specification also fails to provide any implicit or inherent disclosure that administration only inferior to the nose is contemplated. The specification specifically excludes treatment of rhinorrhea as disclosed on page 11. However, the specification, beyond this, fail to limit the administration to any specific location. Thus, administration inferior to the nose cannot be contemplated by the instant specification. Furthermore, the specification specifically contemplates method of controlling mucus secretion associated with cholinergic secretions (see page 10 of the specification). It is well known in the art that mucus secretion is controlled by cholinergic nervous system and this nervous system control exist in the middle ear and controls the pathogenesis of human middle ear effusion. Thus, it cannot be said that only mucus secretion inferior to the nose is implicitly or inherently contemplated.

Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-16 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims have been amended to recite that the botulinum toxin is administered to a human patient "at a location inferior to the nose of the patient." It is unclear what locations are contemplated this amendment. Inferior has multiple definitions, such as of a lesser rank and lower than a given reference point, and thus it is unclear what portions of the body would be "inferior" to the nose.

Furthermore, in claim 19, it is unclear what conditions are associated with the mucus secretion which has a duration less than the longevity of the effect of the administration of the botulinum toxins. The specification is void of any precise definition that would encompass these conditions. Therefore, the claim is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Sanders et al. and Quinn et al. (WO0010598).

The claims have been amended to recite that the botulinum toxin is administered to a human patient "at a location inferior to the nose of the patient."

Sanders et al. Teaches the relaxation of bronchial muscles in asthmatic or COPD patients by the administration of botulinum toxin (see example VIII, col. 10, lines 45-50). The reference discloses that the mode of administration is achieved via an aerosol inhaler (see example VIII). The administration of botulinum toxin to the muscles of COPD patients would necessarily treat muscus secretion because mucus secretion is a hallmark of COPD. Note that Quinn et al. States that COPD is a common respiratory condition, being the fourth most common cause of death in middle age in the Western world. COPD comprises two related diseases, which usually occur together, emphysema and chronic bronchitis. The pathological basis of chronic bronchitis is mucus hypersecretion. The excessive, chronic bronchial secretion results in expectoration, and can last from a few days to many years. The mucus hypersecretion of COPD results in small airway obstruction producing reduced maximal respiratory flow and slow forced lung emptying. There is minimal reversal of the impaired airway function of COPD by bronchodilators and currently no effective therapy for the mucus hypersecretion (col. 1, lines 53-64). Since, mucus secretion occurs in COPD, administration of botulinum toxin to a patient via inhalation would inherently suppress mucus secretion.

Note that the reference is relevant as a 102(b) for the following reasons:

The benefit of the earlier filing date under 35 U.S.C. 120 of the parent application Serial No. 08/627,118 has been denied for claims 1-16 for the instant application. These claims in the instant continuation-in-part application recites a feature, i.e. "wherein the mucus secretion is **not** a symptom of rhinorrhea" and where the mucus is in the respiratory tract. This feature has been first introduced and adequately supported in the instant application 10/087,222 on page 6, and thus such claims are entitled only to the filing date of this application 10/087,222; In re Von Lagenhoven , 458

F.2d 132, 136, 173 USPQ 426, 429 (CCPA 1972) and Chromalloy American Corp. v. Alloy Surfaces Co ., Inc ., 339 F. Supp. 859, 874, 173 USPQ 295, 306 (D. Del. 1972).

6. Claims 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can normally be reached on (571) 272-0974. The fax phone number of this group is (571)-273-8300.

3/28/05

Anish Gupta
Patent Examiner